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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,359	09/10/2004	Johan Bernard Ubbink	3714652.00504	5698
29157	7590	06/24/2010	EXAMINER	
K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690			BADR, HAMID R	
			ART UNIT	PAPER NUMBER
			1781	
			NOTIFICATION DATE	DELIVERY MODE
			06/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No. 10/507,359	Applicant(s) UBBINK ET AL.	
	Examiner HAMID R. BADR	Art Unit 1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on RCE 2/10/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/10/2010 has been entered.

Claims 1, 3, 5-14 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 11-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 11 partially recites the limitation "mixing a first preparation of microorganisms and 40% to 70% , by weight of total dry matter, of at least one carbohydrate selected from the group consisting of maltodextrins, starches, low molecular weight sugars, hydrocolloids and combinations thereof, wherein the microorganisms are embedded in the at least one carbohydrate, drying the first

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preparation to form particles using a drying technique selected from the group consisting of spray drying, fluidized-bed drying, and combinations thereof, mixing the particles and further components to form a second preparation, drying the second preparation to an Aw below 0.3" According to this limitation the first preparation (comprising microorganisms) is dried using the techniques recited in the claim. Then this "first preparation" called "particles" is mixed with further components to form a "second preparation" which is then dried. According to this process, the microorganism are dried twice, first time with the carbohydrate, and second time with further components. The specification as originally filed does not support drying the microorganisms first time with carbohydrates and second time with further components.

3. The Applicants refer to numerous passages in the specification to find support for the above mentioned process. Page 11, lines 31-36, page 4, lines 35 to page 5 line 3, page 11, lines 14-33, , page 11, lines 3-6, page 11, lines 19-25, page 17, line 10 to page 18, line 5, page 11, lines 31-35, page 17, lines 34-36, page 3 line 35 to page 4 line 3, page 9, lines 1-10, page 12, lines 12-14, page 17 line 10 to page 18 line 5 have been referred to by Applicants.

4. None of the referenced pages and passages supports the idea that microorganisms are dried twice, the first time with the carbohydrate (drying to form particles) and the second time with further components (drying the second preparation).

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5. Claims 1 and 11 also recite “a moisture barrier in an amount of about 8% to about 18% of the compacted inner matrix”. The specification does not support the word “about” in this phrase.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 3 and 5-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 1 and 11 are indefinite for “wherein the inner matrix contains 40% to 70%, by weight of total dry matter, of the at least one carbohydrate”. It is not clear whether the inner matrix contains 60% to 30% moisture or the inner matrix is 40% to 70% carbohydrate (w/w) or 40% to 70% of the inner matrix is one type of carbohydrate and the rest 60% to 30% is another type of carbohydrate. The overall phrase is confusing

9. In claim 1, “compacted inner matrix” is recited. In claim 11 “the uncoated pellet” is recited. Therefore, claims 1 and 11 are not consistent regarding the product.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. Claims 1, 3, 5-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casas-Perez (US 5,480,641; hereinafter R1) in view of of Klapwijk et al. (EP 0 298 605; hereinafter R2) and Van Lengerich (WO 99/48372; hereinafter R3).

12. R1 discloses methods and product for direct feed microorganisms such as *Lactobacillus reuteri* delivered in pellets (compacted whey particles) (Abstract).

13. R1 teaches coating the palletized whey particles with lyophilized *L. reuteri* cells suspended in oil (col. 3, lines 55-57) or the suspension of *L. reuteri* in oil is mixed with whey powder and then the mixture is compressed into pellets (compressed whey particles) or tablets. (Col. 3, lines 62-65). Given that oil is impermeable to moisture, the pellet will be impermeable to moisture.

14. It is noted that whey inherently contains lactose in the range of 50-70%, it is clear that an inert carbohydrate is included in the pellets as taught by R1 and as presently claimed. It is also noted that whey contains proteins.

15. The pellets may have different sizes (Col.4, lines 10-20) for instance particles which go through mesh 8 (2.38 mm) but retained by mesh 20 (0.84 mm) or particles going through mesh 0.25 inch (6.35 mm) but retained by mesh 8 (2.38 mm). It is clear that pellets having size between 2.38 mm and 0.25 inch would inherently possess volume as presently claimed.

16. R1 teaches that whey pellets may contain 5×10^7 to about 10^8 cells/g whey (Col. 4, lines 25-27).

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17. Given that the cells are lyophilized (below water activity of 0.3) and the suspending agent and binder is oil and the supporting matrix is whey powder, the water activity of less than 0.3 will be inherent to the pellets.

18. R1 teaches using 1—15 lbs/sq. in pressure to produce the compacted pellets (Col. 4, lines 10-11)

19. R1 is silent regarding the water activity (A_w) of the pellets.

20. R2 discloses the process of making supported lactic acid bacterial compositions where the water activity of the supported flora products is 0.3 or less, particularly 0.2 or less (page 4 line 8). Therefore, the effect of water activity on the shelf life of particles containing lactic acid bacteria was known at the time the invention was made.

21. While R1 teaches of coating the compacted pellets with oil, R1 and R2 are generally silent regarding coating pellets in which the microorganisms are embedded.

22. R3 discloses a product that contains encapsulated live organisms. The matrix composition of his invention comprises a plasticizer and a substantial amount of a free flowing mixture (page 3, lines 8-15). The coating of the pellets is discussed in examples 2 and 3 wherein the pellets have a coating weighing 5%-10% of the weight of pellets. (page 35 and 36).

23. It is also noted that coatings for palletized products containing sensitive materials including microorganisms, enzymes or chemicals play the role of protecting agents against environmental elements such as oxygen, moisture, light etc. as well as being the controlled release agents. A coating of 0.5% to 50% based on the weight of the

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pellets is conventional in the art. Such a range of coating is given by US 6,500,463 (col. 19, line 20 to col. 20 line 3).

24. R3 also discloses the dimensions of the product where the extruded rope may have a cross sectional diameter 0.5 mm to about 3 mm. Assuming an average pellet diameter of 1.75 mm, the pellet volume is calculated to be about 2.8 mm^3

25. R3 describes the product to be non-expanded, non-puffed, and substantially non-cellular. It is also mentioned that the starch is substantially ungelatinized, and not substantially deconstructured or dextrinized. Specific densities of the products are disclosed to be about 0.8 to 1.5 g/cm^3 (Page 33, lines 8-13).

26. R3 teaches of the use of the pellets as food or their incorporation into foods, nutraceuticals and pharmaceuticals. A variety of foods having various moisture levels are mentioned. The product comprises at least one component of the food e.g. yogurt which can contain nonfat dry milk, or gelatin, or lactose (Page 33 line 14 to page 34 line 16).

27. R3 teaches of the incorporation of pellets containing live micro-organisms into various foods where the food and the pelleted product share at least one ingredient. R3 mentions that the encapsulated product may be incorporated, with or without grinding, into foods for human or animal consumption. The foods, which are exemplified do share, at least, one component with the granulated product (Page 33, lines 14-23 and page 34, lines 1-2).

28. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R1 by lowering the water

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activity of the pellets as taught by R2 and coating the pellets as taught by R3 to make the probiotic delivery system as instantly claimed. One would have done so to receive the benefits of a product which could be used as a delivery system for dried viable organisms which could be used in various food and feed applications. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success in making a probiotic delivery system with characteristics as presently claimed.

Response to Arguments

Applicants' arguments have been reviewed thoroughly. These arguments do not deem persuasive for the following reasons:

1. Applicants argue that the amendment in claim 11 is supported by the specification and there is full support for drying the first preparation, adding the first preparation to further components to make the second preparation and drying the second preparation.
 - a. Please see the explanations under 112 (first paragraph) above. None of the passages referred to by Applicants support the idea of drying the organisms twice.
2. Applicants argue about the rejections under 102(b) and 103(a).
 - a. In light of the new ground(s) of rejection, these arguments are moot. However, teachings of EP 0 298 605 are still valid for disclosing the water activity of compositions

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containing lactic acid bacteria. The WO 99/48372 reference is used as a teaching reference for disclosures regarding the coating of particles.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R. Badr
Examiner
Art Unit 1781

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1781